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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,357	09/24/2001	Nicholas F. D'Antonio	DA7119US (#90036)	7922

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,357	Applicant(s) D'ANTONIO ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,12-15,18,19,21,23-35,49,52-58,60,61,63,68 and 88-97 is/are pending in the application.
- 4a) Of the above claim(s) 36-48,50,51,59,62,64-67 and 69-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10,12-15,18,19,21,23-35,49,52-58,60,61,63,68 and 88-91 is/are rejected.
- 7) ☒ Claim(s) 92-97 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 23 (and thus their dependent claims 2, 5-10, 12-15, 18, 19, 21, 23-35, 49, 52-58, 60, 61, 63, 68, 88-97) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 17, recites “a release structure”. It appears that this release structure is the same release apparatus as in line 10. However, the claim recites them as though they are different elements. Clarification is requested.

Claim 23, line 29, recites “a release structure”. It appears that this release structure is the same release apparatus as in line 10. However, the claim recites them as though they are different elements. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2, 5-10, 12-15, 18, 19, 21, 23-35, 49, 53-55, 57, 58, 60, 61, 63, 68, 88-91 are rejected under 35 U.S.C. 102(e) as being anticipated by D'Antonio et al., 6,056,716.

As to claims 1,2, 5, 12, 13, 15, 23, 27, 29, 31, 49, 53, 54, 60, 61, 63, D'Antonio discloses a housing (proximal portion of 707, fig. 7E) for housing at least two injectate cartridges (or containers) (845) each of said cartridges having a dispensing channel with an exit nozzle (842', col. 26, lines 52-54), and a plunger (847, col. 26, line 59) for moving through each of the cartridges to dispense injectate from the cartridges;

a holding member (840) for holding the respective injectate cartridges with said dispensing channels directed in a common direction;

a latching and release apparatus (708, see fig. 7E) included in or on said housing for latching said holding member to said housing and for releasing said holding member and the injectate cartridges held thereby for non-contaminating disposal after the injection process (additionally, the container is spaced away from the housing (see 101 in fig. 7E);

a ram apparatus (848) having separate rams (848), each movable with respect to one of said cartridges to move the respective plungers simultaneously for forcing injectate simultaneously from said cartridges through the dispensing channels and the individual exit nozzle (col. 60-63);

a carriage (849) movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process

a spring apparatus (227, or see column 26, lines 61-64) for moving said carriage from the set position to the dispensing position (for **claims 7-9, 18**, also);

a carriage resetting apparatus (436) for moving said carriage from the dispensing position to the set position and for recocking said spring apparatus, (see column 10, line 46 – column 11, line 20),

and a releasable latching device for latching said spring apparatus is disclosed, (see column 11, lines 14-20) (for **claim 10** also),

said latching and release apparatus (708) supports said holding member spacing the front end of said holding member away from said housing (see figure 7E for assembly) to avoid contact of said housing with any contaminant on the front end of said holding member or the cartridges. (Although holding member 708 is not entirely spaced away from the housing, at least the front end of the holding member is spaced away from the housing)

a release structure (716) operatively connected to said container-holding member and being actuable to release said container-holding member and the injectate containers held in said container-holding member without requiring human contact with said container-holding member or the containers (col. 25, line 65 – col. 26, line 4).

As to claim 6, said release apparatus includes a groove (see front end of 820 in figure 7E, or front end of 836 in figure 7F) in the front plate and a releasable latching member (714, see figure 7E) in the housing.

As to claim 7, a manually operable trigger device (701) is disclosed; wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

As to claims 8-9, a trigger (701) holding a spring/energy storing apparatus (227) in a set condition is disclosed in fig. 2AA and 7A.)

As to claim 10, the locking and release apparatus (708, see fig. 7E) comprises a locking member (712) considered to be cooperating with container-holding member to lock said holding member to said housing, and a releasing apparatus (708) for releasing the locking member and an ejection device for ejecting the container-holding member.

As to claim 14, one of the cartridges are considered inactive, since this is an intended use and the cartridge is capable of being inactive.

As to claim 18, a biasing device (848) for placing pressure on the containers to force the injectate out of the containers at jet velocity is disclosed, (see fig. 7GG).

As to claims 19 and 55, there are six cartridges, see figure 7GG.

As to claim 21, holding member has at least two openings (proximal and distal openings (fig 7GG.)

As to claims 24 and 65, the device further includes a jet injector housing (distal portion of 707) wherein said housing is for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said latching device, said carriage resetting apparatus and said releasable latching device.

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As to claims 25, 89, 90, since it is not clear as to what orifice Applicant is referring, Examiner considers the orifice to be at (842') and the guard plate (or guard wall as to claim 89) is at distal end of (840.)

As to claims 26 and 32, a cam and cam follower as claimed is disclosed, see column 10, lines 46-59.

As to claim 28, a spring apparatus with movable rods (227 or see column 26, lines 61-64) for moving said carriage as claimed is disclosed.

As to claim 30, a solenoid as claimed is disclosed at (48).

As to claims 31 and 33, a drive apparatus moved by a motor driven device (221) is disclosed, see column 9, line 63 – column 10, line 17.

As to claims 34, 88, 91, a loading station with a motor to operate said carriage resetting apparatus is disclosed, see column 10, lines 10-17.

As to claim 35, a sensing apparatus as claimed is disclosed in column 24, lines 24-27.

As to claims 57, the pattern of the holding member is a circle, and there are five exit nozzles equally disposed around the perimeter of the circle, and one exit nozzle disposed at the center of the circle (figure 7GG.

As to claim 58, the pattern of the holding member is a circle, and there are six exit nozzles as claimed (see figure 7GG.)

As to claim 68, the latch and release apparatus (708) is manually actuable.

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2. As to claims 1,2, 5-10, 12-15, 18, 19, 21, 49, 52-55, 60-63, 68, 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Tarello et al., 4,518,384.

As to claims 1,2, 5, 12, 13, 15, 49, 53, 54 and 60-63, Tarello et al. discloses a housing (56 and 60) for housing at least two injectate cartridges (or containers) (18) each of said cartridges having a dispensing channel with an exit nozzle (near 28), and a plunger (30) for moving through each of the cartridges to dispense injectate from the cartridges;

a holding member (14) for holding the respective injectate cartridges with said dispensing channels directed in a common direction;

a latching and release apparatus (54 and 64, see col. 5, line 14 and fig. 1) included in or on said housing for latching said holding member to said housing and for releasing said holding member and the injectate cartridges held thereby for non-contaminating disposal after the injection process;

and a releasable latching device (54 and 64) for latching said spring apparatus is disclosed,

said latching and release apparatus (54 and 64) supports said holding member spacing the front end of said holding member away from said housing (see figure 2) to avoid contact of said housing with any contaminant on the front end of said holding member or the cartridges. (The front end of the holding member is spaced away from the housing)

a release structure (54) operatively connected to said container-holding member and being actuable to release said container-holding member and the injectate containers held in said container-holding member without requiring human contact with said container-holding member or the containers. (Although the reference does not disclose that structure 54 is released without

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requiring human contact with the container-holding member or the containers, it appears that member 14 is released by a pushing action on member 14. This action can be made using an object, for example, a table, and thus does not require human contact with the container-holding member or the containers.)

As to claim 6, said release apparatus includes a groove (64) in the front plate and a releasable latching member (see fig. 1) in the housing.

As to claim 7, a manually operable trigger device (12) is disclosed; wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

As to claims 8-9, a trigger (12) holding a spring/energy storing apparatus (68) in a set condition is disclosed, (see fig. 2.)

As to claim 10, the locking and release apparatus (34, 54 and 64) comprises a locking member (64, see fig. 1) cooperating with container-holding member to lock said holding member to said housing, and a releasing apparatus (34) for releasing the locking member and an ejection device for ejecting the container-holding member.

As to claim 14, one of the cartridges are considered inactive, since this is an intended use and the cartridge is capable of being inactive.

As to claim 18, a biasing device 68() for placing pressure on the containers to force the injectate out of the containers at jet velocity is disclosed, (see fig. 2)

As to claims 19 and 55, there are six cartridges, see figure 2. (The Office notes that the claims do not require that there be only six cartridges.)

As to claim 21, holding member has at least two openings (proximal and distal end of 14, see fig. 2.)

As to claim 90, since it is not clear as to what orifice Applicant is referring, Examiner considers the orifice to be (near 28, see fig. 3)

As to claim 68, the latch and release apparatus (54 and 64) is manually actuatable.

Allowable Subject Matter

3. Claims 92-97 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are not persuasive.

Applicant argues on page 31 that D'Antonio et al. do not disclose a structure for releasing a member for holding the containers or cartridges without requiring human contact with either the holding member or the containers. Applicant argues that D'Antonio et al. in column 27, lines 3-6, discloses that the capsules can be loaded in the system by sliding the barrel forward and the barrel is then slid back into position to lock the capsules in place. Applicant states that this is all done manually, and the user must touch both the container-holding apparatus and the container. This is not persuasive because the passage mentioned by Applicant refers to loading the

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capsules, not removing them. D'Antonio in column 25, line 65 to column 24, line 4, discloses specifically that a spring (717) ejects the capsule when door (708) is opened; "thus, physical contact and the risk of cross-injection for the health worker is further reduced when the injection is completed".

Applicant also argues on page 31 that Tarello et al. likewise states that a clip includes a structure for retaining the cartridges "suitable for manual handling and interconnection with the medicament discharging device 12". As stated above, although the reference does not disclose that structure 54 is released without requiring human contact with the container-holding member or the containers, it appears that member 14 is released by a pushing action on member 14. This action can be made using an object, for example, a table, and thus does not require human contact with the container-holding member or the containers

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 


LONG V. LE
SUPERVISORY PATENT EXAMINER
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01/23/06